CV 16 4038

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

DeARCY HALL, J.

LEVY, M.J.

UNITED STATES OF AMERICA *ex rel.* Samuel Caughron, M.D., and **SAMUEL CAUGHRON, M.D.,** individually, Plaintiffs, v. **GENOMIC HEALTH, INC.,** Defendant.

COMPLAINT

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)

JURY TRIAL DEMANDED

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff and *qui tam* Relator, Samuel Caughron, M.D., ("Caughron" or "Relator"), by and through his undersigned counsel The JTB Law Group, LLC alleges as follows:

I. PRELIMINARY STATEMENT

1. This is a *qui tam* action on behalf of the United States of America (the "Government") under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, and the common law to recover treble damages sustained by, and civil penalties and restitution owed to, the Government as a result of a scheme by Defendant Genomic Health, Inc. ("GHI" or the "Company"), in illicit cooperation with hospitals in this District and elsewhere, to circumvent certain regulations governing the reimbursement by Medicare for medical services, in violation of those regulations and several federal statutes.

2. Under this scheme, GHI arranged with hospitals in this District and across the country to falsely and without medical necessity misrepresent the order dates for a certain

laboratory test, when that test was performed for Medicare patients, in order to shift the cost from the hospitals to the Medicare program.

3. By means of this scheme, GHI has enriched and continues to enrich these hospitals; has secured and continues to secure or retain business for itself; and has defrauded and continues to defraud the Government of many millions of dollars.

4. In order to effectuate this scheme, GHI knowingly (a) caused to be presented or presented false claims to Medicare; (b) made or caused to be made or used false records or statements material to these false claims; and (c) conspired to cause these claims to be presented and/or these records or statements to be made or used, causing Medicare to pay many millions of dollars in reimbursements that should not have been paid.

5. As a Medicare provider, GHI is statutorily obligated to "assure" that it provides its services "economically." *See* 42 U.S.C. § 1320c-5.

6. GHI is also statutorily prohibited from offering or paying any "remuneration," which "include[s] any kickback, bribe, or rebate," to induce any person or entity to purchase or recommend any of GHI's services that are covered by Medicare. *See* 42 U.S.C. § 1320a-7b(b) (the "Anti-Kickback Statute" or the "AKS").

7. In order to receive Medicare reimbursement, a provider such as GHI must submit a claim form on which it must certify, *inter alia*, that the information therein is "true, accurate and complete," and that the claim "complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment," including the two statutes mentioned above. *See* CMS-1500, attached hereto as **Exhibit A**, at 2.

8. Although GHI was obviously aware of these laws and regulations, the Company nevertheless offered, and continues to offer, an arrangement that allows hospitals to retain for

their own beneficial use more of each payment they receive for the care of Medicare-enrolled patients, as an inducement for the hospitals to order GHI's test – for which GHI then seeks reimbursement directly from Medicare.

9. In effectuating this scheme, GHI violates at least 42 U.S.C. § 1320c-5 and the AKS, and it also makes certifications that are both factually and legally false.

10. Each of these violations can serve as a predicate for liability under the False Claims Act.

11. On information and belief, GHI's scheme has been highly lucrative for both the company and the hospitals involved. For the year ended December 31, 2015, the Company reported that "more than 107,030 Onco*type* DX test reports were delivered for use in treatment planning, compared to more than 95,630 and 85,510 test reports delivered for the years ended December 31, 2014 and 2013, respectively."[1] In that period the Company derived revenue of $58.9 million from tests performed for Medicare-enrolled patients, and it had an additional $5.7 million in Medicare receivables.[2]

12. On information and belief, the Company was not legitimately entitled to most of those monies.

13. This Complaint has been filed *in camera* and under seal pursuant to 31 U.S.C. § 3730(b)(2). It will not be served on Defendant unless and until the Court so orders. A copy of the Complaint, along with written disclosure of substantially all material evidence and information that Relator possesses, has been served contemporaneously herewith on the Attorney

[1] Form 10-K for the Fiscal Year ending December 31, 2015, *available at* http://www.wikinvest.com/stock/Genomic_Health_(GHDX)/Filing/10-K/2016/F128790636 (last accessed May 16, 2016), at 51.

[2] *Id.*, at 55, 60.

General of the United States and the United States Attorney for the Eastern District of New York, pursuant to 31 U.S.C. § 3730(b)(2) and Fed. R. Civ. P. 4(d).

II.
JURISDICTION AND VENUE

14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, because this action is brought for violations of the False Claims Act, 31 U.S.C. § 3729 *et seq.* (as amended); 42 U.S.C. § 1320c-5; and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, all of which are federal statutes. The Court has subject matter jurisdiction over the common law claims pursuant to 28 U.S.C. § 1345.

15. The Court has personal jurisdiction over Defendant because Defendant has at least minimum contacts with the United States. Moreover, Defendant is licensed to transact and does transact business in this District, has carried out its fraudulent scheme in this District, and facilitates, within this District, the submission of false claims for excessive payment and for payment in violation of the AKS. The Complaint has been filed timely within the period prescribed by 31 U.S.C. § 3731(b).

16. Venue is proper in this District pursuant to 31 U.S.C. §§ 3732(a) and 28 U.S.C. § 1391 (b)(2). Defendant can be found in, is licensed to do business in, and transacts or has transacted business in this District, and events and omissions that give rise to these claims have occurred in this District. This District is a locus of the fraud.

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III.
NO PUBLIC DISCLOSURE; DIRECT AND INDEPENDENT KNOWLEDGE OF VIOLATIONS OF THE FALSE CLAIMS ACT

17. There has been no public disclosure, relevant under 31 U.S.C. § 3730(e), of the "allegations or transactions" in this Complaint.

18. Relator has direct and independent knowledge of the information on which the allegations in this Complaint are based. Relator voluntarily provided the information to the Government before filing this suit.

19. Relator is the original source of the information he has given to the Government regarding Defendant's knowing engagement in conduct violative of federal law, and resulting in the payment by the Government of the false or fraudulent claims that Defendant made and caused to be made. This conduct includes, but is not limited to, violations of 31 U.S.C. § 3729(a)(1).

IV.
THE PARTIES

A. PLAINTIFF AND RELATOR

20. Plaintiff the United States of America brings this action by and through Relator Samuel Caughron, M.D. ("Caughron" or "Relator"). At all times relevant to this Complaint, the United States funded the provision by Defendant GHI of medical testing for eligible individuals through the Medicare program, acting through the Centers for Medicare & Medicaid Services ("CMS"), which was formerly known as the Health Care Financing Administration, within the United States Department of Health and Human Services ("HHS"). Thus, the United States brings this action on behalf of its agencies, CMS and HHS, and on behalf of the Medicare program.

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21. Relator Caughron also brings this action on behalf of himself and the United States.

22. Caughron is a citizen of the United States and, at all relevant times, has been a resident of Jackson County, State of Missouri.

23. Caughron, a physician, is a Fellow of the College of American Pathologists and is Board Certified in Anatomic and Clinical Pathology and Molecular Genetic Pathology. He is Laboratory Medical Director for Shawnee Mission Medical Center, in Merriam, Kansas, and is also Director of the Molecular Lab at MAWD Pathology Group, PA, in North Kansas City, Missouri.

24. In his capacity as Laboratory Medical Director for Shawnee Mission Medical Center and his capacity as Director of the Molecular Lab at MAWD Pathology Group, Caughron acquired information that GHI was and is violating the False Claims Act and other federal statutes and regulations.

B. DEFENDANT

25. Defendant Genomic Health, Inc. is a corporation formed and existing under the laws of the State of Delaware.

26. On its website, GHI promotes itself as "the world's leading provider of genomic-based diagnostic tests."[3]

27. As relevant here, GHI provides a proprietary laboratory test with the registered trademark "Onco*type* DX."

28. GHI's principal executive offices are located at 301 Penobscot Drive, Redwood City, California.

[3] *See* http://www.genomichealth.com/en-US/who_we_are/our_mission (last accessed May 7, 2016).

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29. GHI's registered agent for service of process is Corporation Service Company, 2711 Centerville Rd., Suite 400, Wilmington, Delaware 19808.

30. GHI is licensed by several states, including the State of New York, to perform laboratory procedures, including Oncotype DX testing, at its Redwood City location.[4]

31. On information and belief, GHI has performed and is continuing to perform Oncotype DX testing on biologic specimens from patients in hospitals located in this District.

V.
STATEMENT OF BACKGROUND FACTS

A. MEDICARE

32. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare program, to pay for certain healthcare services provided to certain segments of the population. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 1395 *et seq*.

33. HHS, through CMS, administers the Medicare program.

34. Part B of the Medicare program authorizes payment of federal funds for medical and other health services, including services provided by hospitals and medical testing laboratories. *See* Medicare Benefit Policy Manual, Chapter 15, § 30.4 (2012).

35. Medicare Part B is funded by insurance premiums paid by enrolled Medicare beneficiaries and contributions from the federal treasury. Eligible individuals who are age 65 or older, or disabled, may enroll in Part B to obtain benefits in return for payments of monthly premiums as established by HHS. 42 U.S.C. §§ 1395j, 1395o, 1395r.

36. Individuals or entities who are participating providers in Medicare, such as

[4] *See* http://www.genomichealth.com/Licenses_accreditations (last accessed May 7, 2016).

Defendant, may seek reimbursement from CMS for services rendered to patients who are program beneficiaries, provided that the services are rendered in compliance with the laws, rules, regulations, policies and procedures governing reimbursement.

37. CMS enters into agreements with providers such as GHI to establish their eligibility to participate in the Medicare program. During the times relevant herein, to be eligible for payment under Part B of the program, a provider must certify as follows:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. ... I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.

CMS Form-855B (07/11), at 31.

38. In addition, in order to receive reimbursement, a provider such as GHI must submit a claim form for each covered service or item, in which the provider must certify that "the information [therein] is true, accurate and complete," and the claim "complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as the Stark law)." CMS-1500 (approved OMB-0938-1197 form 1500 (02-12)), at 2.

B. THE DRG PROSPECTIVE PAYMENT SYSTEM AND THE "14-DAY RULE"

39. Hospitals are reimbursed prospectively for services provided to Medicare-enrolled patients according to the Diagnosis-Related Group or "DRG" into which the patients fall.

40. A hospital patient is assigned a DRG according to his or her principal and secondary diagnoses under the International Classification of Diseases ("ICD"), as well as his or her gender, age, treatment procedure, discharge status, and the presence of complications or

comorbidities.

41. The DRG prospective payment system was first implemented nationwide in 1983 by the Healthcare Financing Administration, now CMS. The history, design, and classification rules of the DRG system are set out in the CMS DRG Definitions Manual. There are 999 separate DRGs, including several catch-all DRGs, in the current DRG Definitions Manual, ICD-10-CM/PCS MS-DRGv30.0.[5]

42. The DRG system is intended to describe all types of hospital patients, and to provide a hospital with a fixed and standardized reimbursement based on the services that patients in each DRG are expected to need. The system thus is intended to prompt hospitals to provide the most efficient care possible and keep costs down.

43. The DRG prospective payment system is used for all Medicare-enrolled inpatients. A particular DRG payment is intended to prospectively reimburse a hospital for all the care and services it provides to a Medicare-enrolled inpatient who falls into that DRG.

44. In 2007, however, CMS enacted a special rule governing reimbursement for testing for Medicare patients performed by third-party laboratories, that is, a facility other than the treating hospital itself. This rule is 42 C.F.R. § 414.510 – the "14-Day Rule" (also known as the "Date of Service Rule" or "DOS Rule").

45. Under the 14-Day Rule, tests for Medicare inpatients performed by third-party laboratories,

a. must be billed by the laboratory *to the hospital* if the test is ordered during the patient's stay or within 14 days after discharge;

b. may be billed by the laboratory *directly to Medicare* if the test is ordered 14 days or more after discharge.

[5] *See* https://www.cms.gov/icd10manual/version30-fullcode-cms/P0001.html (last accessed May 8, 2016).

See 42 C.F.R. § 414.510; *see also* Bruce Quinn, M.D., Ph.D., "Discoveries in Health Policy: Babe Ruth and the 14 Day Rule" (Feb. 16, 2015).[6]

46. In other words, the hospital must reimburse the laboratory for tests ordered less than 14 days after discharge, but is *not* obligated to reimburse the laboratory for tests ordered 14 days or more after discharge.

47. When a hospital must reimburse a third-party laboratory for a test ordered less than 14 days from discharge, that reimbursement has the effect of diminishing the value of the fixed DRG payment the hospital received for that patient.

48. However, when a test is conducted ***14 or more*** days after discharge, then the hospital does not have to reimburse the third-party laboratory out of its fixed DRG payment.

49. Because it reimburses the laboratory ***in addition to*** the DRG payment it makes to the hospital, CMS ultimately pays more for the totality of the care of a patient whose test is ordered ***later*** than it does for the care of a patient whose test is ordered ***sooner***, within the 14 day window.

C. GHI'S ONCOTYPE DX TESTING

50. In or around 2004, GHI developed a proprietary laboratory test which it calls "Onco*type* DX."[7] The test was first used "to predict the likelihood of cancer recurrence and the likelihood of chemotherapy benefit in early stage invasive breast cancer patients."[8] The Company has since adapted the technology for use in testing for patients with cancers of the colon or the prostate.[9]

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[6] http://www.discoveriesinhealthpolicy.com/2015/02/babe-ruth-and-14-day-rule.html (last accessed May 19, 2016).
[7] Form 10-K for the Fiscal Year ending December 31, 2015, *available at* http://www.wikinvest.com/stock/Genomic_Health_(GHDX)/Filing/10-K/2016/F128790636 (last accessed May 16, 2016), at 51.
[8] *Id.*
[9] *Id.*

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51. According to GHI's website, "Oncotype DX testing helps patients and their physicians to optimize their cancer care and outcomes, enabling many patients to avoid unnecessary procedures and therapies, and saving the healthcare system billions of dollars in unnecessary costs."[10]

52. Also according to the website, "over half a million patients … in more than 90 countries" have had Oncotype DX tests as part of their treatment.[11]

53. The company's website describes Oncotype DX as "Genomic Health's flagship line of gene expression test."[12]

54. GHI has reported the results of a physician survey "demonstrat[ing] that physicians ***frequently changed treatment recommendations*** for [certain classes of] breast cancer patients" after obtaining the results of Oncotype DX testing.[13] (emphasis added).

55. As of February 29, 2016, the list price for an Onco*type* DX breast cancer test in the United States was $4,620; the list price for an Onco*type* DX colon cancer test was $4,420; and the list price of an Onco*type* DX prostate cancer test was $4,520.[14]

56. In the Fiscal Year ending December 31, 2015, GHI derived almost $290 million in revenue from its Oncotype DX testing.[15]

57. $58.9 million, or 20% of that revenue, was attributable to testing performed for Medicare-enrolled patients and reimbursed directly by CMS.[16] As of December 31, 2015, the Company had an additional $5.7 million in Medicare receivables.[17]

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[10] http://www.genomichealth.com/oncotype_iq_products/oncotype_dx (last accessed May 9, 2016).

[11] *Id.*

[12] http://www.oncotypedx.com/ (last accessed May 9, 2016).

[13] http://www.drugs.com/clinical_trials/genomic-health-announces-results-clinical-survey-showing-oncotype-dx-changes-recommendations-women-8638.html (last accessed May 16, 2016).

[14] Form 10-K for the Fiscal Year ending December 31, 2015, *available at* http://www.wikinvest.com/stock/Genomic_Health_(GHDX)/Filing/10-K/2016/F128790636 (last accessed May 16, 2016), at 51.

[15] *Id.*, at 55 (showing revenue of $287,458, 000 for the period).

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58. As of October 2015, CMS reimbursed GHI $3,416 for each Oncotype DX breast cancer test performed for a Medicare-enrolled patient.[18]

D. GHI'S SCHEME

59. Relator Caughron first became aware of the 14-Day Rule in connection with his work as Director of a medical laboratory.

60. At some point, Caughron began to suspect that some laboratories and/or hospitals were intentionally delaying or rescheduling tests or holding specimens in order to take advantage of the 14-Day Rule, to the possible detriment of Medicare patients whose tests were delayed and with the certain consequence of causing the Government, through its CMS program, to pay separately for these tests, so that the hospitals could avoid absorbing their cost.

61. On or about February 19, 2016, Caughron had separate recorded telephone conversations with two representatives of GHI about the 14-Day Rule.

62. Caughron spoke first with Amy Hussel, who identifies herself in her LinkedIn profile as a "Regional Oncogenomic Liaison at Genomic Health Inc.," in the Cedar Rapids, Iowa area. *See* **Exhibit B.**

63. A full transcript of the recording of that conversation is attached hereto as **Exhibit C.**

64. On the call, Hussel told Caughron about how other hospitals she works with "flag" orders for Oncotype DX tests for Medicare patients so that the hospitals "don't end up with the bill."

65. Hussel said, "[W]hat I usually recommend obviously with the 14 just as soon as they walk out of the hospital the 15th day then order the Oncotype …" but that GHI has "some

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[16] *Id.*
[17] *Id.*, at 60.
[18] http://investor.genomichealth.com/releasedetail.cfm?releaseid=935522, *last accessed May 9, 2016.*

things that are in-house, that have been put in place" so that a Medicare order is "***canceled*** [by GHI] if it's within that 14 days." (emphasis added).

66. Caughron then had a longer conversation with Eric Johnson, who identifies himself in his LinkedIn profile as "Senior Regional Sales Manager at GHI," in the Indianapolis, Indiana area. *See* **Exhibit D**.

67. A full transcript of the recording of Caughron's conversation with Johnson is attached hereto as **Exhibit E**.

68. Johnson confirms Hussel's description of GHI's practice:

a. "[W]hat we have chosen to do is, because most hospitals say, 'Oh, I don't want to pay the bill,' ah, what we do is we ***cancel the order ... we notify the treating physician that it was canceled because it was under 14 days***, and, and, you know, if, if after 15 days they want to reorder, then they can reorder and we will bill Medicare." (emphasis added).

b. "[A hospital has] to opt in to it, you know, you have to sign an agreement saying 'Yes, we want you to bill us.' If you don't sign that, then we say, 'Well, we don't have an agreement, you know, to bill the hospital.' ***We'll cancel the test, we'll notify everybody it's been canceled 'cause of the 14-Day Rule***, and if after 14 days they would like to reorder, then we will reorder it, and, you know, and send the paperwork out, have them re-sign it, then it starts the clock at, you know, 17 or 18 or 20 days. And then Genomic Health bills it, which is really what we like to do because of the fact that, you know, the turn-around time for Medicare is like seven days for billing and, ah, it really is, ah, it's – it's a lot of extra paperwork for everybody and we're pretty good at billing it, so …." (emphasis added).

c. "I'm doing customer service work on, on a case right now and that's exactly what it is, is the, the collection date is less than 14 days from the date of signature, and what we've done is ***we've canceled the order***, and that, you know, so now, we're contacting the account, just, to tell the account it's less than 14 days, you know, and that way the, the hospital doesn't get the bill on it." (emphasis added)

d. "[W]e cross-check everything internally because we, we understand completely that, you know – you know, $4,000 bill, you know, when you don't expect it … is a lot of money. So our goal is not to have those …."

69. Johnson also gave some indications of the extent of GHI's fraudulent scheme:

a. "[W]e've been doing this procedure [Oncotype DX testing] for, what's it, like the last five years, and there have been I think two or three times that I can remember out of thousands of tests that we've had where for some reason we, we missed it [i.e., the hospital was billed]. But ah, in my region there, you know, knock on wood, have – there haven't been any …."

b. In Caughron's area, "probably seven out of ten" of GHI's accounts use the company's online ordering system, which "flags" tests for Medicare patients that are ordered before the 14th day.

c. Johnson names a hospital in Chicago – Advocate Christ Medical Center – that "does probably 300 [Oncotype DX] assays a year," and "absolutely none" of whatever portion of those were for Medicare patients have been billed to the hospital.

d. In response to Caughron's question, Johnson clarifies that the 14-Day Rule, and GHI's practice of canceling "early" orders, applies whether the Oncotype DX test is used for breast, prostate, or colon cancer.

70. Johnson mentioned "a letter that explains all this," and offered to send Caughron a copy. Sometime after their conversation on February 19, Johnson sent Caughron that letter by email; a copy is attached hereto as **Exhibit F** (the "GHI Letter").

71. The GHI Letter is directed to the Company's "Valued Customer[s]," and bears the legend "Effective Date: 17-Oct-2013." *Id.*

72. The GHI Letter reads, in pertinent part, as follows:

> We at Genomic Health, Inc. wish to inform you of Medicare billing rules that affect the way we are required to bill Onco*type* DX® tests for Medicare Beneficiaries. ….
>
> In January 2007, the Centers for Medicare and Medicaid Services (CMS) revised the billing rules that apply to laboratory services performed on stored specimens.
>
> The Medicare "Date of Service" (DOS) payment rule addresses the date of service for laboratory specimens which in turn dictates who according to Medicare rules and regulations, must accept responsibility for billing the laboratory service.
>
> Under current Medicare regulations –
>
> • If the Onco*type* DX test is **ordered less than 14 days from the patient's**

> surgical procedure, the date of service is the date the specimen (biopsy or lumpectomy) was collected and the hospital is generally required to bill for the test.
>
> - If the Oncotype DX test is ordered 14 or more days after the date of discharge, then the date of service is the date the test was performed, and Genomic Health will bill for the test.
>
> Should your institution submit an order for the Oncotype DX test which falls within the Medicare DOS rule, a Genomic Health Customer Relations Representative will contact you to discuss entering into an agreement with GHI regarding financial responsibility. Specifically, Genomic Health will agree to provide the Oncotype DX test to your patients when the test is ordered less than 14 days from hospital discharge assuming your facility accepts financial responsibility for the test as required by Medicare billing rules. By signing that contract, your facility agrees that it will accept financial responsibility for timely-billed tests pursuant to the DOS rules.
>
> Without the executed contract, please understand that state and federal anti-inducement laws create a potential compliance risk for us and you, thus we are not permitted to perform the services unless the hospital agrees to pay for the service. Failure to execute a financial responsibility agreement will result in test order cancellation, and a Customer Relations Representative will notify the ordering physician. If no further instructions concerning handling of the tissue sample are provided at that time, a Customer Service representative will follow up with the ordering physician to obtain directions for handling of the tissue specimen.

Id. (emphasis in original).

73. Although couched as simply informative, the GHI Letter in fact invites "valued customers" to collude with GHI in circumventing the very Medicare regulations that the letter purports only to explain – in violation of the "federal anti-inducement laws" mentioned therein, and in violation of the requirement that Medicare-paid services be provided "economically."

74. The GHI Letter describes "test order cancellation" as an undesirable consequence of a hospital's "failure" to enter into a "financial responsibility agreement" with GHI – the same agreement that Johnson referenced in his telephone conversation with Caughron.

75. However, as both Hussel and Johnson made clear in their telephone conversations with Caughron, GHI actually cancels orders placed within 14 days of specimen collection ***as a***

beneficial service to the hospitals, so that they "don't end up with the bill" – and so that GHI can seek full reimbursement directly from CMS.

76. In the scheme described by Hussel and Johnson and outlined in the GHI Letter, GHI cancels test orders strictly for financial reasons, without any regard whatsoever for the medical needs or the comfort of the patients involved.

77. The speed with which a patient and his or her doctor receive the results of the Oncotype DX test can have considerable bearing on the patient's comfort and well-being, as evidenced by comments posted by patients on an online discussion board maintained by Breastcancer.org:[19]

a. On December 30, 2014, a breast-cancer sufferer with the screenname "Hotrodmommy" wrote: "Onc[ologist] sent out for Oncotype DX on Dec 4th, well that's what I thought. I've been waiting for the results, since the Onc hadn't called I called yesterday, I had to do my own research to find out that the the [*sic*] test was never requested. When I informed the nurse that information she said that ***when she sent the request it must have not gone through***, and thanked me for letting her know. "WHAT" are you kidding me!! This was kinda of important to me since I'm in a grey area already due to ITC in nodes and LVI on wether [*sic*] or not to do chemo. Has this happened to any of you ladies??? ***This makes me very nervous about having to wait so long to start chemo if I need it. I've heard that you should start chemo 4 to 8 weeks after surgery***. (emphasis added).

b. The same day, another user with the screenname "momof2doxies" responded: "It happened to me in 2012 with my first tumor. ***The test was ordered but the hospital had to be contacted 3 times by Genomic Health that the sample had not been received***. This of course happened during the holiday period and delayed my treatment by several weeks." (emphasis added).

c. A user with the screenname "daisylover" also responded: "I also needed to 'remind' my oncologist about the OncotypeDX test – even though he recommended it originally. It's important to have the results, though. I think that everyone worries about delays in treatment .... When you have your OncotypeDX score and can make a treatment plan, you will feel less scared, more in control."

[19] https://community.breastcancer.org/forum/147/topics/827263 (last accessed May 16, 2016).

d. On January 3, 2015, a user with the screenname "doxie" responded: "I too had a delay in getting my Onco[type DX] score .... It took 5 weeks. ***Took 3 weeks to figure out that the tissue had not made it out of the hospital.***" (emphasis added).

e. On January 22, 2015, a user with the screenname "twolumps" responded: "I had my BMX [*i.e.*, bilateral mastectomy] on Dec. 2nd, had to wait until Dec. 31st to see the MO who then finally ordered the oncotype. Sample was not received until last week (***hospital didn't send it!***) .... Had felt really positive every step of the way up until this last wait for the oncotype." (emphasis added).

78. As can be seen from this small sampling of online comments, having to wait for the results of Oncotype DX testing – no matter the reason for that wait – is not a trivial matter to patients.

79. By enabling a hospital to retain more of the DRG payments it receives for Medicare patients for whom Oncotype DX testing is ordered and performed, GHI knowingly and willfully provides a financial benefit to induce that hospital to order products and services – namely, more Oncotype DX tests – for which payment will then be made in whole or in part by the Medicare program.

80. By billing Medicare directly, rather than having the hospital pay for the test out of its DRG payments, GHI causes CMS to pay out more, in total, than it otherwise would for the test. In so doing, GHI knowingly and willfully ignores its legal obligation to "assure" that the test, to be paid for by Medicare, "will be provided economically." *See* 42 U.S.C. § 1320c-5.

81. Meanwhile, Medicare-enrolled patients wait for their test results, and suffer because of that wait.

82. GHI's practice is not the industry norm; other laboratories have disavowed any willingness to circumvent the 14-Day Rule. For instance, in an online "frequently asked questions" sheet about the Rule, Foundation Medicine, Inc., states "Canceling a test is not a

problem ***as long as the decision to do so is guided by appropriate clinical judgment and not to avoid the application of Medicare billing rules.***"[20]

83. GHI has canceled and reordered, and continues to cancel and reorder, Oncotype DX testing for Medicare patients not based on ***any*** clinical judgment but rather ***entirely*** in order to avoid the application of Medicare billing rules.

VI.
THE STATUTORY FRAMEWORK

84. In order to receive reimbursement for covered services, a provider such as GHI must submit a claim form. *See* **Exhibit A**. That claim form requires the provider to make the following certification:

> In submitting this claim for payment from federal funds, I certify that: 1) ***the information on this form is true, accurate and complete***; 2) I have familiarized myself with all applicable laws, regulations, and program instructions, which are available from the Medicare contractor; 3) I have provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision; 4) ***this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute*** and Physician Self-Referral law (commonly known as Stark law) ....

Id., at 2 (emphasis added).

85. Under Section 1156 of the Social Security Act, 42 U.S.C. § 1320c-5, it is the obligation of any provider of health care services or items for which payment may be made (in whole or in part) by Medicare "to assure, to the extent of his authority, that services or items ordered or provided ... ***will be provided economically*** ...." (emphasis added).

86. Under this statute, "the entitlement to Medicare reimbursement depends upon fulfilling an obligation to perform services economically." *United States ex rel. Kneepkins v.*

[20] http://www.foundationmedicine.com/wp-content/uploads/2015/11/FMI-Medicare-Date-of-Service-FAQ-2015-10-28.pdf (last accessed May 16, 2016) (emphasis added).

Gambro Healthcare, Inc., 115 F. Supp. 2d 35, 43 (D. Mass. 2000). The statute thus "primarily protects the government from wasteful payments to [providers] engaged in Medicare fraud." *Nayyar v. Mt. Carmel Health Sys.*, No. 2:10-cv-00135, 2010 U.S. Dist. LEXIS 77565, at *7 (S.D. Ohio July 1, 2010).

87. The Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (the "AKS"), reflects, in part, congressional desire to protect patients and federal healthcare programs, including Medicare, from the harms that could occur if third-party medical service providers were allowed to provide or arrange for financial benefits to flow to those institutions that made use of the third party's services or products. To that end, Congress chose to prohibit the payment of kickbacks in any form.

88. Congress first enacted the AKS in 1972, and strengthened it in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Publ. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Anti-fraud and Abuse Amendments, Publ. L. No. 95-142; Medicare and Medicaid Patient Program Protection Act of 1987, Pub. L. No. 100-93.

89. In pertinent part, the AKS makes it illegal for individuals or entities to "offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) ... to any person to induce such person ... to order ... any ... service, or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2)(B).

90. An arrangement in which GHI circumvents or manipulates the 14-Day Rule so that hospitals can retain a larger portion of the DRG payments received for particular patients, thereby encouraging hospitals to continue using GHI's services, violates the AKS.

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91. Violation of the AKS is a felony punishable by fines and imprisonment, and can also result in exclusion from participation in federal health care programs. 42 U.S.C. § 1320a-7b(b)(2) and 42 U.S.C. § 1320a-7(b)(7).

92. The False Claims Act, 31 U.S.C. §§ 3729 (the "FCA"), in turn, reflects Congress's objective to "enhance the Government's ability to recover losses as a result of fraud against the Government." S. Rep. No. 99-345, at 1 (1986). As relevant here, the FCA establishes treble damages liability for an individual or entity that:

a. "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(l) (2000) and, as amended, 31 U.S.C. § 3729(a)(l)(A);

b. "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim, *id.* § 3729(a)(l)(B); or

c. "conspires to defraud the Government by getting a false or fraudulent claim allowed or paid," *id.* § 3729(a)(3)(1986), and, as amended, 31 U.S.C. § 3729(a)(l)(C).[21]

93. "Knowing," within the meaning of the FCA, is defined to include reckless disregard and deliberate indifference. *Id.*

94. In addition to treble damages, the FCA also provides for assessment of a civil penalty for each violation or each false claim.[22]

95. Finally, the FCA also provides for payment of a percentage of the Government's recovery to a private individual who brings suit on behalf of the Government (the "Relator") under the FCA. *See* 31 U.S.C. § 3730(d).

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[21] On May 20, 2009, the False Claims Act was amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 ("FERA"). Section 3729(a)(l)(B) was formerly Section 3729(a)(2), and is applicable to Defendant's conduct for the entire time period alleged herein by virtue of Section 4(f) of FERA, while Sections 3279(a)(l) and 3279(a)(3) of the FCA prior to FERA, and as amended in 1986, remain applicable here for conduct predating the effective date of FERA.

[22] FCA civil penalties are $5,500 to $11,000 for violations occurring on or after September 29, 1999, such as those alleged herein, pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes) and 64 Fed. Reg. 47099, 47103 (1999).

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96. Failure to comply with the Anti-Kickback Statute in connection with a claim submitted to a federally funded insurance program is actionable under the FCA. Under the Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub. L. No. 111- 148, 6402(f), 124 Stat. 119, codified at 42 U.S.C. § 1320a-7b(g), "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA]."

VII.
FIRST CLAIM FOR RELIEF
FEDERAL FALSE CLAIMS ACT: PRESENTATION OF FALSE CLAIMS

97. Caughron repeats and realleges all preceding paragraphs of the Complaint inclusive, as if fully set forth herein.

98. Throughout the statutory period, GHI presented claims to CMS for reimbursement for Oncotype DX testing that misrepresented the dates on which that test was ordered, in order to shift the obligation to pay for that testing from the hospital ordering the testing to Medicare.

99. GHI did so by arranging with the hospitals to cancel tests that had been ordered during the patient's stay or within fourteen days of her discharge, and to re-order them at some time fifteen days or more after discharge – i.e., outside of the 14-Day Rule.

100. The tests were canceled without regard to the patient's medical needs or mental welfare.

101. The tests were canceled solely to avoid the application of Medicare billing rules and to enable GHI to pass along a benefit to the hospital.

102. Thus, the "date of service" on each form submitted to CMS for reimbursement for Onctoype DX testing was fraudulent.

103. Furthermore, when it submitted each such claim, GHI certified that "the information on [the] form [was] true, accurate and complete," when GHI knew that this was not the case.

104. Each such certification was therefore factually false.

105. Accordingly, GHI knowingly presented false or fraudulent claims to CMS for payment in violation of 31 U.S.C. § 3729(a)(l) (2000), and, as amended, 31 U.S.C. § 3729(a)(l)(A).

106. The submission by GHI of these false claims and certifications caused the Government, through its agency CMS and that agency's Medicare program, to pay out sums that it would not have paid if CMS had been made aware of the falsity of GHI's claims and certifications.

107. Each false or fraudulent claim submitted to the United States is a separate violation of the FCA.

108. By reason of the false or fraudulent claims that GHI knowingly presented, the United States has been damaged, and continues to be damaged, in a substantial amount to be proven at trial. Relator therefore respectfully requests an order awarding the United States treble damages plus a civil monetary penalty for each violation, and awarding Relator the maximum award permitted under 31 U.S.C. § 3730(d).

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)

VIII.
SECOND CLAIM FOR RELIEF
FEDERAL FALSE CLAIMS ACT: PRESENTATION OF FALSE CLAIMS

109. Caughron repeats and realleges all preceding paragraphs of the Complaint inclusive, as if fully set forth herein.

110. With each claim that GHI submitted to CMS for reimbursement for Oncotype DX testing throughout the statutory period, GHI provided a benefit to the ordering hospital to induce that hospital to continue ordering Oncotype DX testing, as described herein.

111. Each time GHI did so, it violated the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (the "AKS").

112. Under 42 U.S.C. § 1320a-7b(g), each such claim was therefore "a false or fraudulent claim for purposes of [the False Claims Act]."

113. Furthermore, when it submitted each such claim, GHI expressly certified that the claim "complie[d] with … the Federal anti-kickback statute," when GHI knew that this was not the case.

114. Each such certification was therefore legally false.

115. Accordingly, GHI knowingly presented false or fraudulent claims to CMS for payment in violation of 31 U.S.C. § 3729(a)(l) (2000), and, as amended, 31 U.S.C. § 3729(a)(l)(A).

116. The submission by GHI of these false certifications, statements, or representations caused the Government, through its agency CMS through and that agency's Medicare program, to pay out sums that it would not have paid if CMS had been made aware of the falsity of GHI's certifications, statements, or representations.

117. Each false or fraudulent claim submitted to the United States is a separate violation of the FCA.

118. By reason of the false or fraudulent claims that GHI knowingly presented, the United States has been damaged, and continues to be damaged, in a substantial amount to be proven at trial. Relator therefore respectfully requests an order awarding the United States treble damages plus a civil monetary penalty for each violation, and awarding Relator the maximum award permitted under 31 U.S.C. § 3730(d).

IX.
THIRD CLAIM FOR RELIEF
FEDERAL FALSE CLAIMS ACT: PRESENTATION OF FALSE CLAIMS

119. Caughron repeats and realleges all preceding paragraphs of the Complaint inclusive, as if fully set forth herein.

120. Each claim that GHI submitted to CMS for reimbursement for Oncotype DX testing throughout the statutory period, rather than having the ordering hospital pay for the test out of its DRG payments, caused CMS to pay out more, in total, than it otherwise would for the test.

121. By submitting such claims, GHI knowingly and willfully ignored its obligation under 42 U.S.C. § 1320c-5 to "assure" that the test, to be paid for by Medicare, would be "provided economically."

122. When it submitted each such claim, GHI certified that the claim "complie[d] with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment." Each such certification therefore implied GHI's compliance with 42 U.S.C. § 1320c-5, when GHI knew that this was not the case.

123. Each such implied certification was therefore legally false.

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)

124. Accordingly, GHI knowingly presented false or fraudulent claims to CMS for payment in violation of 31 U.S.C. § 3729(a)(l) (2000), and, as amended, 31 U.S.C. § 3729(a)(l)(A).

125. The submission by GHI of these false certifications, statements, or representations caused the Government, through its agency CMS through and that agency's Medicare program, to pay out sums that it would not have paid if CMS had been made aware of the falsity of GHI's certifications, statements, or representations.

126. Each false or fraudulent claim submitted to the United States is a separate violation of the FCA.

127. By reason of the false or fraudulent claims that GHI knowingly presented, the United States has been damaged, and continues to be damaged, in a substantial amount to be proven at trial. Relator therefore respectfully requests an order awarding the United States treble damages plus a civil monetary penalty for each violation, and awarding Relator the maximum award permitted under 31 U.S.C. § 3730(d).

X.
FOURTH CLAIM FOR RELIEF
FEDERAL FALSE CLAIMS ACT: MAKING OR USING FALSE RECORD OR STATEMENT TO CAUSE FALSE CLAIM TO BE PAID

128. Caughron repeats and realleges all preceding paragraphs of the Complaint inclusive, as if fully set forth herein.

129. As described above, throughout the statutory period, GHI knowingly and falsely certified, stated, and/or represented that, in seeking reimbursement for Oncotype DX testing that it performed for Medicare patients, the Company was in full compliance with applicable federal and state laws, including but not limited to 42 U.S.C. § 1320c-5 and the AKS.

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130. As described above, used false records and statements when it submitted these claims for reimbursement.

131. Accordingly, GHI knowingly used false records or statements material to false or fraudulent claims to CMS for payment in violation of 31 U.S.C. § 3729(a)(l)(B).

132. The submission by GHI of these false records or statements caused the Government, through its agency CMS and through that agency's Medicare program, to pay out sums that it would not have paid if CMS had been made aware of the falsity of GHI's records or statements.

133. Each submission of a false record or statement is a separate violation of the FCA.

134. By reason of the false or fraudulent records or statements that GHI knowingly submitted, the United States has been damaged, and continues to be damaged, in a substantial amount to be proven at trial. Relator therefore respectfully requests an order awarding the United States treble damages plus a civil monetary penalty for each violation, and awarding Relator the maximum award permitted under 31 U.S.C. § 3730(d).

XI.
FIFTH CLAIM FOR RELIEF
FEDERAL FALSE CLAIMS ACT: CONSPIRING TO SUBMIT FALSE CLAIMS

135. Caughron repeats and realleges all preceding paragraphs of the Complaint inclusive, as if fully set forth herein.

136. As set forth above, GHI conspired with various hospitals to circumvent the 14-Day Rule, so that those hospitals would be able to retain more of the DRG payments they received for Medicare patients for whom Oncotype DX testing was ordered and performed.

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137. By means of this scheme, GHI knowingly and willfully provided a financial benefit to induce that hospital to order GHI's Oncotype DX testing, for which payment was then made in whole or in part by the Medicare program, in violation of the AKS.

138. Accordingly, GHI knowingly conspired to defraud the Government by getting false or fraudulent claims allowed or paid, in violation of 31 U.S.C. § 3729(a)(3) (1986), and conspired to commit violations of 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B), in violation of 31 U.S.C. § 3729(a)(1)(C) (2009).

139. By reason of the false or fraudulent claims that GHI and the hospitals conspired to get allowed or paid, or by reason of their conspiracy to violate 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B), the United States has been damaged, and continues to be damaged, in a substantial amount to be proven at trial. Relator therefore respectfully requests an order awarding the United States treble damages plus a civil monetary penalty for each violation, and awarding Relator the maximum award permitted under 31 U.S.C. § 3730(d).

XII.
SIXTH CLAIM FOR RELIEF
UNJUST ENRICHMENT

140. Caughron repeats and realleges all preceding paragraphs of the Complaint inclusive, as if fully set forth herein.

124. As set forth above, the Government issued Medicare reimbursements to GHI based on false or fraudulent claims for Oncotype DX testing, which GHI was able to perform (and seek reimbursement for) as a result of enabling cooperating hospitals to illicitly obtain a financial benefit, in violation of federal laws and regulations, including but not limited to 42 U.S.C. § 1320c-5 and the AKS.

125. The circumstances of GHI's receipt from the Government of these monies, in an

amount to be determined at trial, as a result of enabling these hospitals to illicitly obtain financial benefits are such that, in equity and in good conscience, GHI should not retain such monies.

126. By reason of GHI's unjust enrichment, Relator respectfully requests an order requiring GHI to disgorge all monies the Company earned as a result of the illicit scheme described herein, and awarding Relator the maximum award permitted under 31 U.S.C. § 3730(d).

PRAYER FOR RELIEF

WHEREFORE, Relator respectfully requests that this Court enter judgment in his favor and that of the United States, and against Defendant GHI, granting the following:

(A) On the First, Second, Third, Fourth, and Fifth Claims for Relief (violations of the FCA, 31 U.S.C. §§ 3729(a)(l), 3729(a)(2), and 3729(a)(3), and, as amended, 31 U.S.C. §§ 3729(a)(l)(A), 3729(a)(l)(B), and 3729(a)(l)(C)), an award to the United States for treble its damages, in an amount to be determined at trial, plus a penalty in the amount of $11,000 for each false claim submitted in violation of the FCA;

(B) On the First, Second, Third, Fourth, and Fifth Claims for Relief, an award to the United States for its costs pursuant to 31 U.S.C. § 3729(a)(3);

(C) On the First, Second, Third, Fourth, and Fifth Claims for Relief, an award to Relator in the maximum amount permitted under 31 U.S.C. § 3730(d);

(D) On the Sixth Claim for Relief; an award for the damages sustained and amounts by which GHI retained illegally obtained monies, plus interest, costs, and expenses;

(E) And on all Claims for Relief,

1. An award to Relator of the reasonable attorneys' fees, costs, and expenses he incurred in prosecuting this action;
2. An award to the United States and to Relator for their costs of court;
3. An award to the United States and to Relator for pre- and post-judgment interest at the rates permitted by law; and

(F) An award of such other and further relief as this Court may deem to be just and proper.

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)

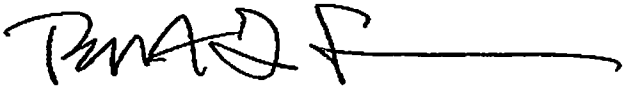
DEMAND FOR TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Relator demands trial by jury on all questions of fact raised by the Complaint.

Dated: July 21, 2016

Respectfully submitted,

JTB LAW GROUP, LLC



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CERTIFICATE OF SERVICE

I hereby certify that on July 21, 2016 I caused a true copy of the Complaint in the matter captioned *United States of America ex rel. Samuel Caughron, M.D. v. Genomic Health, Inc.* to be served upon the following, along with written disclosure of substantially all material evidence and information possessed by Relator:

by hand delivery to
Kenneth Abell
Assistant United States Attorney
United States Department of Justice
United States Attorney's Office
Eastern District of New York
271 Cadman Plaza East
Brooklyn, NY 11201

by USPS Registered Mail, Return Receipt Requested, to
Office of the Attorney General of the United States
United States Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

Patrick S. Almonrode